

EXHIBIT I

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MUTUAL PHARMACEUTICAL
COMPANY, INC., AR SCIENTIFIC,
INC., and AR HOLDING COMPANY,
INC.

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

MUTUAL PHARMACEUTICAL
COMPANY, INC., et al.,

Plaintiffs,

v.

WATSON PHARMACEUTICALS, INC.,
et al.,

Defendants.

Civil Action No. 09-5421(GEB)(TJB)

**OBJECTIONS AND RESPONSES OF
PLAINTIFFS MUTUAL
PHARMACEUTICAL COMPANY, INC.,
AR SCIENTIFIC INC., AND AR HOLDING
COMPANY, INC. TO DEFENDANT
WEST-WARD PHARMACEUTICAL
CORP.'S FIRST SET OF REQUESTS FOR
ADMISSION**

Pursuant to Federal Rules of Civil Procedure Rule 36, Plaintiffs Mutual Pharmaceutical Company, Inc., AR Scientific, Inc., and AR Holding Company, Inc. (collectively, "Plaintiffs") respond to the First Set of Requests for Admission ("Requests") propounded by Defendant West-Ward Pharmaceutical Corp. ("Defendant" or "West-Ward") as follows.

I. GENERAL RESPONSES AND OBJECTIONS

1. Plaintiffs' responses to the Requests for Admission are made to the best of Plaintiffs' present knowledge, information, and belief. Plaintiffs' investigation of the facts relating to this action is ongoing and not yet completed, and as such said responses to the Requests for Admission are at all times subject to such additional or different information that discovery or further investigation may disclose and, while based on the present state of Plaintiffs' recollection, is subject to such refreshing of recollection, and such additional knowledge of facts, as may result from their further discovery or investigation.

2. Plaintiffs reserve the right to make any use of, or to introduce at any hearing and at trial, information and/or documents responsive to the Requests for Admission but discovered subsequent to the date of this response, including, but not limited to, any such information or documents obtained in discovery herein.

3. Plaintiffs reserve all objections or other questions as to the competency, relevance, materiality, privilege, or admissibility as evidence of these responses in any subsequent proceeding or trial of this or any other action for any purpose whatsoever.

4. Plaintiffs reserve the right to object on any ground at any time to such other or supplemental Requests for Admission as Defendant may at any time propound involving or relating to the subject matter of these Requests for Admission.

5. Plaintiffs object to the extent that any Requests for Admission seek information or production of documents protected by the attorney-client privilege or the work product doctrine. Such information or documents shall not be provided in response to the Requests for Admission and any inadvertent disclosure or production thereof shall not be deemed a waiver of any privilege with respect to such information or documents or of any work product immunity which may attach thereto.

6. Plaintiffs object to the introductory definitions and instructions in the Requests for Admission to the extent they purport to enlarge, expand, or alter in any way the plain meaning and scope of any specific Request for Admission on the ground that such enlargement, expansion, or alteration renders said Request for Admission vague, ambiguous, unintelligible, unduly broad, and uncertain.

II. SPECIFIC OBJECTIONS AND RESPONSES TO REQUESTS FOR ADMISSION

Without waiving or limiting in any manner any of the foregoing General Responses and Objections, but rather incorporating them into each of the following responses to the extent applicable, Plaintiffs respond to the specific Requests for Admission as follows.

Request for Admission No. 1:

Admit that your unapproved colchicine tablets were still being sold by Wholesalers or pharmacies as recently as 2010.

Response to Request for Admission No. 1:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs contacted Wholesalers in July 2006 and informed them that Plaintiffs had discontinued the sale of all unapproved products, including unapproved colchicine. However, Plaintiffs lack information sufficient to admit or deny this Request, and on that basis deny this Request, because Plaintiffs do not know when the Wholesalers and pharmacies stopped selling Plaintiffs' unapproved colchicine product.

Request for Admission No. 2:

Admit that your unapproved colchicine tablets were still being sold by Wholesalers or pharmacies as recently as 2009.

Response to Request for Admission No. 2:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs contacted Wholesalers in July 2006 and informed them that Plaintiffs had discontinued the sale of all unapproved products, including unapproved colchicine. However, Plaintiffs lack information sufficient to admit or deny this Request, and on that basis deny this Request, because Plaintiffs do not know when the

Wholesalers and pharmacies stopped selling Plaintiffs' unapproved colchicine product.

Request for Admission No. 3:

Admit that your unapproved colchicine tablets were still being sold by Wholesalers or pharmacies as recently as 2008.

Response to Request for Admission No. 3:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs contacted Wholesalers in July 2006 and informed them that Plaintiffs had discontinued the sale of all unapproved products, including unapproved colchicine. However, Plaintiffs lack information sufficient to admit or deny this Request, and on that basis deny this Request, because Plaintiffs do not know when the Wholesalers and pharmacies stopped selling Plaintiffs' unapproved colchicine product.

Request for Admission No. 4:

Admit that your unapproved colchicine tablets were still being sold by Wholesalers or pharmacies as recently as 2007.

Response to Request for Admission No. 4:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs contacted Wholesalers in July 2006 and informed them that Plaintiffs had discontinued the sale of all unapproved products, including unapproved colchicine. However, Plaintiffs lack information sufficient to admit or deny this Request, and on that basis deny this Request, because Plaintiffs do not know when the Wholesalers and pharmacies stopped selling Plaintiffs' unapproved colchicine product.

Request for Admission No. 5:

Admit that you sold colchicine tablets without FDA-approval as recently as 2007.

Response to Request for Admission No. 5:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs deny this Request. Plaintiffs stopped selling all unapproved products, including unapproved colchicine in July 2006.

Request for Admission No. 6:

Admit that you sold colchicine tablets without FDA-approval as recently as 2006.

Response to Request for Admission No. 6:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs admit this Request. Plaintiffs stopped selling all unapproved products, including unapproved colchicine in July 2006.

Request for Admission No. 7:

Admit that you sold colchicine tablets without FDA-approval as recently as 2005.

Response to Request for Admission No. 7:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs admit this Request. Plaintiffs stopped selling all unapproved products, including unapproved colchicine in July 2006.

Request for Admission No. 8:

Admit that you utilized Price Lists to market your colchicine tablets prior to obtaining FDA approval for COLCRYS.

Response to Request for Admission No. 8:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs admit this Request. Plaintiffs contacted Price Lists in July 2006 and informed them that Plaintiffs had discontinued the sale of all unapproved products, including unapproved colchicine, and requested that all of Plaintiffs' unapproved products, including unapproved colchicine, be removed from the Price Lists.

Request for Admission No. 9:

Admit that you submitted information about your colchicine products to Price Lists prior to obtaining FDA approval for COLCRYS.

Response to Request for Admission No. 9:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs admit this Request. Plaintiffs contacted Price Lists in July 2006 and informed them that Plaintiffs had discontinued the sale of all

unapproved products, including unapproved colchicine, and requested that all of Plaintiffs' unapproved products, including unapproved colchicine, be removed from the Price Lists.

Request for Admission No. 10:

Admit that your colchicine tablets were listed on Price Lists prior to obtaining FDA approval for COLCRYS.

Response to Request for Admission No. 10:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs admit this Request. Plaintiffs contacted Price Lists in July 2006 and informed them that Plaintiffs had discontinued the sale of all unapproved products, including unapproved colchicine, and requested that all of Plaintiffs' unapproved products, including unapproved colchicine, be removed from the Price Lists.

Request for Admission No. 11:

Admit that your colchicine tablets were listed on Wholesaler Ordering Systems prior to obtaining FDA approval for COLCRYS.

Response to Request for Admission No. 11:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs admit this Request. Plaintiffs contacted Wholesalers in July 2006 and informed them that Plaintiffs had discontinued the sale of all unapproved products, including unapproved colchicine, and requested that all of Plaintiffs' unapproved products, including unapproved colchicine, be removed from the Wholesaler Ordering Systems.

Request for Admission No. 12:

Admit that your colchicine tablets were listed on Wholesaler Ordering Systems after you stopped selling unapproved colchicine tablets.

Response to Request for Admission No. 12:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs contacted Wholesalers in July 2006 and informed them that Plaintiffs had discontinued the sale of all unapproved products, including

unapproved colchicine. However, Plaintiffs lack information sufficient to admit or deny this Request, and on that basis deny this Request, because Plaintiffs do not know when Plaintiffs' unapproved colchicine product was removed from the Wholesaler Ordering Systems.

Request for Admission No. 13:

Admit that your colchicine tablets were listed on Price Lists after you stopped selling unapproved colchicine tablets.

Response to Request for Admission No. 13:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs contacted Price Lists in July 2006 and informed them that Plaintiffs had discontinued the sale of all unapproved products, including unapproved colchicine. However, Plaintiffs lack information sufficient to admit or deny this Request, and on that basis deny this Request, because Plaintiffs do not know when Plaintiffs' unapproved colchicine product was removed from the Price Lists.

Request for Admission No. 14:

Admit that you made no effort to have your colchicine products removed from any Price Lists prior to January 1, 2006.

Response to Request for Admission No. 14:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs admit this Request. Plaintiffs contacted Price Lists in July 2006 and informed them that Plaintiffs had discontinued the sale of all unapproved products, including unapproved colchicine, and requested that all of Plaintiffs' unapproved products, including unapproved colchicine, be removed from the Price Lists.

Request for Admission No. 15:

Admit that you made no effort to have your colchicine products removed from any Wholesaler Ordering Systems prior to January 1, 2006.

Response to Request for Admission No. 15:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs admit this Request. Plaintiffs contacted

Wholesalers in July 2006 and informed them that Plaintiffs had discontinued the sale of all unapproved products, including unapproved colchicine, and requested that all of Plaintiffs' unapproved products, including unapproved colchicine, be removed from the Wholesaler Ordering Systems.

Request for Admission No. 16:

Admit that you have never requested that any Wholesaler Ordering System or Price List remove your unapproved colchicine products from their databases.

Response to Request for Admission No. 16:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs deny this Request. Plaintiffs contacted Wholesalers and Price Lists in July 2006 and informed them that Plaintiffs had discontinued the sale of all unapproved products, including unapproved colchicine, and requested that all of Plaintiffs' unapproved products, including unapproved colchicine, be removed from the Wholesaler Ordering Systems and Price Lists.

Request for Admission No. 17:

Admit that you sold at least one drug other than colchicine without FDA approval for such drug.

Response to Request for Admission No. 17:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs admit this Request. Plaintiffs discontinued the sale of all unapproved products, including unapproved colchicine, in July 2006.

Request for Admission No. 18:

Admit that you currently sell at least one drug without FDA approval for such drug.

Response to Request for Admission No. 18:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs deny this Request. Plaintiffs discontinued the sale of all unapproved products, including unapproved colchicine, in July 2006.

Request for Admission No. 19:

Admit that you currently sell more than one drug without FDA approval for such drug.

Response to Request for Admission No. 19:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs deny this Request. Plaintiffs discontinued the sale of all unapproved products, including unapproved colchicine, in July 2006.

Request for Admission No. 20:

Admit that the FDA has not taken any enforcement action against West-Ward's colchicine tablets.

Response to Request for Admission No. 20:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs lack information sufficient to admit or deny this Request and on that basis deny this Request.

Request for Admission No. 21:

Admit that the FDA has not taken expressly required West-Ward to cease its distribution of colchicine tablets.

Response to Request for Admission No. 21:

Plaintiffs incorporate the above-stated general responses and objections herein. Subject to and without waiving the foregoing objections, Plaintiffs lack information sufficient to admit or deny this Request and on that basis deny this Request.

Request for Admission No. 22:

Admit that you have asked the FDA to take action against the sale of unapproved colchicine tablets.

Response to Request for Admission No. 22:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs also object to this Request on the ground that it seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Plaintiffs admit this Request.

Request for Admission No. 23:

Admit that you have asked the FDA to take action against West-Ward's sale of colchicine tablets.

Response to Request for Admission No. 23:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs also object to this Request on the ground that it seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Plaintiffs admit this Request.

Request for Admission No. 24:

Admit that you have received complaints about the safety of your COLCRYS tablets.

Response to Request for Admission No. 24:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs also object to this Request on the ground that it seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Plaintiffs deny this Request.

Request for Admission No. 25:

Admit that you have received complaints about the effectiveness of your COLCRYS tablets.

Response to Request for Admission No. 25:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs also object to this Request on the ground that it seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Plaintiffs admit that they received adverse drug experience reports relating to the effectiveness of COLCRYS.

Request for Admission No. 26:

Admit that you have received complaints about the side effects related to your COLCRYS tablets.

Response to Request for Admission No. 26:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs also object to this Request on the ground that it seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Plaintiffs admit that they received adverse drug experience reports relating to side effects of COLCRYS.

Request for Admission No. 27:

Admit that you have received complaints about the price of your COLCRYS tablets.

Response to Request for Admission No. 27:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs also object to this Request on the ground that it seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Plaintiffs admit this Request.

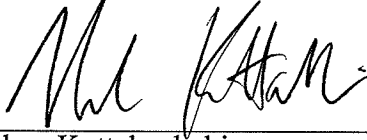
Request for Admission No. 27:

Admit that, to the extent any confusion exists in the marketplace regarding the FDA-approval status of colchicine tablets, your marketing of unapproved colchicine tablets prior to obtaining FDA-approval contributed to such confusion.

Response to Request for Admission No. 27:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs also object to this Request on the ground that it calls for a legal conclusion. Subject to and without waiving the foregoing objections, Plaintiffs lack information sufficient to admit or deny this Request and on that basis deny this Request.

Respectfully Submitted,



Dated: June 22, 2010

Nishan Kottahachchi

COOLEY GODWARD KRONISH LLP

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Attorneys for Plaintiffs

MUTUAL PHARMACEUTICAL COMPANY, INC., AR

SCIENTIFIC, INC., and AR HOLDING COMPANY, INC.

CERTIFICATE OF SERVICE

I hereby certify that on June 22, 2010, a true and correct copy of the foregoing **OBJECTIONS AND RESPONSES OF PLAINTIFFS MUTUAL PHARMACEUTICAL COMPANY, INC., AR SCIENTIFIC INC., AND AR HOLDING COMPANY, INC. TO DEFENDANT WEST-WARD PHARMACEUTICAL CORP.'S FIRST SET OF REQUESTS FOR ADMISSION** has been served by First Class Mail, postage prepaid, addressed to the following individuals:

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Arnall Golden Gregory LLP
171 17th Street NW, Suite 2100
Atlanta, Georgia 30363
Attorney for West-Ward Pharmaceutical Corp.

David Novack, Esq.
Budd Larner, P.C.
150 John F. Kennedy Pkwy.
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Attorney for Excellium Pharmaceutical, Inc.

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EXHIBIT J

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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

MUTUAL PHARMACEUTICAL
COMPANY, INC., et al.,

Plaintiffs,

v.

WATSON PHARMACEUTICALS, INC.,
et al.,

Defendants.

WEST-WARD PHARMACEUTICAL
CORP.,

Counterclaimant,

v.

MUTUAL PHARMACEUTICAL
COMPANY, INC., et al.,

Counterdefendants.

Civil Action No. 09-5421(GEB)(TJB)

**PLAINTIFF MUTUAL PHARMACEUTICAL
COMPANY, INC.'S OBJECTIONS AND
RESPONSES TO DEFENDANT WEST-
WARD PHARMACEUTICAL CORP.'S
FIRST SET OF INTERROGATORIES**

Pursuant to Federal Rules of Civil Procedure Rules 26 and 33, Plaintiffs Mutual Pharmaceutical Company, Inc., AR Scientific, Inc., and AR Holding Company, Inc. (collectively, "Plaintiffs") respond to the First Set of Interrogatories ("Interrogatories") propounded by Defendant West-Ward Pharmaceutical Corp. ("Defendant" or "West-Ward") as follows.

I. GENERAL RESPONSES AND OBJECTIONS

1. Plaintiffs' responses to the Interrogatories are made to the best of Plaintiffs' present knowledge, information, and belief. Plaintiffs' investigation of the facts relating to this action is ongoing and not yet completed, and as such said responses to the Interrogatories are at all times subject to such additional or different information that discovery or further investigation may disclose and, while based on the present state of Plaintiffs' recollection, is subject to such refreshing of recollection, and such additional knowledge of facts, as may result from their further discovery or investigation.

2. Plaintiffs reserve the right to make any use of, or to introduce at any hearing and at trial, information and/or documents responsive to the Interrogatories but discovered subsequent to the date of this response, including, but not limited to, any such information or documents obtained in discovery herein.

3. Plaintiffs reserve all objections or other questions as to the competency, relevance, materiality, privilege, or admissibility as evidence of these responses in any subsequent proceeding in or trial of this or any other action for any purpose whatsoever.

4. Plaintiffs reserve the right to object on any ground at any time to such other or supplemental interrogatories as Defendant may at any time propound involving or relating to the subject matter of these Interrogatories.

5. Plaintiffs object to the extent that any Interrogatory seeks information or production of documents protected by the attorney-client privilege or the work product doctrine. Such information or documents shall not be provided in response to the Interrogatories and any inadvertent disclosure or production thereof shall not be deemed a waiver of any privilege with respect to such information or documents or of any work product immunity which may attach thereto.

6. Plaintiffs object to the introductory definitions and instructions in the Interrogatories to the extent they purport to enlarge, expand, or alter in any way the plain meaning and scope of any specific Interrogatory on the ground that such enlargement, expansion, or alteration renders said Interrogatory vague, ambiguous, unintelligible, unduly broad, and uncertain.

7. Plaintiffs object to each Interrogatory to the extent that it attempts to include several separate interrogatories or discreet sub-parts within one purported Interrogatory. Plaintiffs will not respond to any interrogatories that, including discrete subparts, exceed the applicable limit under the Federal Rules of Civil Procedure.

II. SPECIFIC OBJECTIONS AND RESPONSES TO INTERROGATORIES

Without waiving or limiting in any manner any of the foregoing General Responses and Objections, but rather incorporating them into each of the following responses to the extent applicable, Plaintiffs respond to the specific Interrogatories as follows.

Interrogatory No. 1:

Identify the persons most knowledgeable about the manufacturing, marketing, sale, and distribution of your colchicine tablets.

Response to Interrogatory No. 1:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs further object on the ground that this Interrogatory is compound and attempts to include several separate interrogatories or discreet sub-parts within one purported Interrogatory, and on the ground that it seeks information beyond the possession, custody or control of the Plaintiffs to the extent that it relates to persons other than current employees of the Plaintiffs.

Subject to and without waiving the foregoing objections, Plaintiffs identify the following individuals as most knowledgeable about the manufacturing, marketing, sale, and distribution of Plaintiffs' COLCRYS® colchicine product:

Gregory Hayer
Senior Vice President of Business Development & Market Access
Mutual Pharmaceutical Company, Inc.
1100 Orthodox St.

Philadelphia, PA 19124-3131
Tel: 215-288-6500

Brendan Magrab
Executive Vice President of Commercial Operations and General Counsel
Mutual Pharmaceutical Company, Inc.
1100 Orthodox St.
Philadelphia, PA 19124-3131
Tel: 215-288-6500

Dwight Hanshew
Senior Vice President of Operations
Mutual Pharmaceutical Company, Inc.
1100 Orthodox St.
Philadelphia, PA 19124-3131
Tel: 215-288-6500

Shawn Watson
Director of CMS Chemistry
Mutual Pharmaceutical Company, Inc.
1100 Orthodox St.
Philadelphia, PA 19124-3131
Tel: 215-288-6500

Interrogatory No. 2:

Identify the persons most knowledgeable about your efforts, as alleged in Paragraph 95 of the Complaint, to “create and maintain a stockpile of COLCRYSTM in order to meet anticipated demand for the product.”

Response to Interrogatory No. 2:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs further object on the ground that this Interrogatory seeks information beyond the possession, custody or control of the Plaintiffs to the extent that it relates to persons other than current employees of the Plaintiffs. Subject to and without waiving the foregoing objections, Plaintiffs identify the following individuals as most knowledgeable about Plaintiffs’ efforts to create and maintain a stockpile of COLCRYS® in order to meet anticipated demand for the product:

Gregory Hayer
Senior Vice President of Business Development & Market Access
Mutual Pharmaceutical Company, Inc.
1100 Orthodox St.
Philadelphia, PA 19124-3131

Tel: 215-288-6500

Dwight Hanshew
Senior Vice President of Operations
Mutual Pharmaceutical Company, Inc.
1100 Orthodox St.
Philadelphia, PA 19124-3131
Tel: 215-288-6500

Kurt Nielsen, Ph.D.
Executive Vice President of Pharmaceuticals
Mutual Pharmaceutical Company, Inc.
1100 Orthodox St.
Philadelphia, PA 19124-3131
Tel: 215-288-6500

Interrogatory No. 3:

Identify the persons most knowledgeable about the steps taken by Plaintiffs to list your colchicine products on Price Lists, Wholesaler Ordering Systems, drug ordering systems used by drug store chains, Internet websites or online databases.

Response to Interrogatory No. 3:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs further object on the ground that this Interrogatory seeks information beyond the possession, custody or control of the Plaintiffs to the extent that it relates to persons other than current employees of the Plaintiffs. Subject to and without waiving the foregoing objections, Plaintiffs identify the following individual as most knowledgeable about the steps taken by Plaintiffs to list their COLCRYS® colchicine product on Price Lists and Wholesaler Ordering Systems:

Gregory Hayer
Senior Vice President of Business Development & Market Access
Mutual Pharmaceutical Company, Inc.
1100 Orthodox St.
Philadelphia, PA 19124-3131
Tel: 215-288-6500

Interrogatory No. 4:

Identify each person who has had communications with any manufacturer of colchicine, including, but not limited to, the Sanmar facility in Krishnagiri District, Tamil Nadu, India (the

“Sanmar Facility”) that produces raw colchicine material for Plaintiffs.

Response to Interrogatory No. 4:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs object to this Interrogatory on the ground that the term “raw colchicine” is vague and ambiguous. Plaintiffs further object on the ground that this Interrogatory is overly broad and unduly burdensome to the extent it seeks identification of every individual who has had communications with any manufacturer that produces colchicine material for Plaintiffs, including but not limited to individuals who are not employed by or otherwise managed or controlled by Plaintiffs. Plaintiffs also object to this Interrogatory on the ground that it seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence, and on the ground that it seeks information beyond the possession, custody or control of the Plaintiffs to the extent that it relates to persons other than current employees of the Plaintiffs..

Subject to and without waiving the foregoing objections, Plaintiffs identify the following individuals who are most knowledgeable about communications with manufacturers of colchicine material for Plaintiffs’ COLCRYST[®] product:

Dwight Hanshew
Senior Vice President of Operations
Mutual Pharmaceutical Company, Inc.
1100 Orthodox St.
Philadelphia, PA 19124-3131
Tel: 215-288-6500

Kurt Nielsen, Ph.D.
Executive Vice President of Pharmaceuticals
Mutual Pharmaceutical Company, Inc.
1100 Orthodox St.
Philadelphia, PA 19124-3131
Tel: 215-288-6500

Shawn Watson
Director of CMS Chemistry
Mutual Pharmaceutical Company, Inc.
1100 Orthodox St.
Philadelphia, PA 19124-3131
Tel: 215-288-6500

Interrogatory No. 5:

Identify each individual that you intend to call as a witness at trial.

Response to Interrogatory No. 5:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs further object to this Interrogatory on the ground that it is premature because the discovery process is ongoing. Plaintiffs further object to this Interrogatory on the ground that it calls for information protected by the work-product doctrine.

Subject to and without waiving the foregoing objections, Plaintiffs will identify any witnesses they intend to call at trial in connection with the pretrial conference scheduled by the Court, pursuant to the Federal Rules of Civil Procedure, the Local Rules, and any applicable orders issued by the Court.

Interrogatory No. 6:

Describe in detail any and all efforts made by you to secure a sufficient quantity of colchicine "to meet anticipated demand for the product."

Response to Interrogatory No. 6:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs further object to this Interrogatory on the ground that it seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence, and on the ground that it calls for the disclosure of confidential and proprietary information.

Interrogatory No. 7:

Identify with specificity any documents relating to your efforts to obtain colchicine from manufacturers of the product.

Response to Interrogatory No. 7:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs object to this Interrogatory on the ground that the phrase "manufacturers of the product" is vague and ambiguous. Plaintiffs further object on the grounds that this Interrogatory is overly broad and unduly burdensome, seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence, and calls for the disclosure of confidential and proprietary information.

Interrogatory No. 8:

State the amount of COLCRYSTM tablets in your possession, custody or control (in bottles and tablets).

Response to Interrogatory No. 8:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs object to this Interrogatory on the ground that it calls for the disclosure of confidential and proprietary information.

Subject to and without waiving the foregoing objections, Plaintiffs will respond to this Interrogatory upon entry of a suitable protective order.

Interrogatory No. 9:

Describe in detail all communications that you have had with any individual or entity regarding the quality of West-Ward's colchicine tablets, including, but not limited to, communications relating to West-Ward's FDA-approval status, the safety of West-Ward's colchicine tablets, the labeling of West-Ward's colchicine tablets, or West-Ward's legal right to distribute, market or sell its colchicine tablets.

Response to Interrogatory No. 9:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs object to this Interrogatory on the ground that it is overly broad, unduly burdensome, and calls for the disclosure of confidential and proprietary information. Plaintiffs further object to this Interrogatory to the extent that it calls for information protected by the attorney-client privilege and work-product doctrine. Plaintiffs also object on the ground that this Interrogatory is compound and attempts to include several separate interrogatories or discreet sub-parts within one purported Interrogatory.

Subject to and without waiving the foregoing objections, Plaintiffs will respond to this Interrogatory upon entry of a suitable protective order.

Interrogatory No. 10:

Describe in detail any false or misleading statements that you contend were made by Defendant West-Ward with respect to its colchicine products.

Response to Interrogatory No. 10:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs object to this Interrogatory on the ground that it is premature because the discovery process is ongoing.

Subject to and without waiving the foregoing objections, upon information and belief, West-Ward falsely represents that its unapproved colchicine product is FDA-approved to Price Lists, which are integrated in pharmacy computer systems, to Wholesaler Ordering Systems, and to other advertising and distribution channels. The label and product insert for West-Ward's unapproved colchicine product also does not contain critical safety information, including numerous warnings on drug-drug interactions, food interactions, and contraindications, which is likely to lead to confusion regarding the quality of, and risks associated with, West-Ward's unapproved colchicine product and makes Plaintiffs' FDA-approved COLCRYS® product appear more dangerous than West-Ward's unapproved colchicine product.

Interrogatory No. 11:

Describe with specificity any "misleading, obsolete and/or incomplete information" about its colchicine products that West-Ward has allegedly supplied to "Price Lists, Wholesaler Ordering Systems, and other advertising channels," as you allege in Paragraph 109 of the Complaint.

Response to Interrogatory No. 11:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs object to this Interrogatory on the ground that it is premature because the discovery process is ongoing.

Subject to and without waiving the foregoing objections, upon information and belief, the label and product insert for West-Ward's unapproved colchicine product does not warn patients about the potential for serious drug-drug interactions (e.g. ketoconazole and nefazodone) and food interactions (e.g. grapefruit and grapefruit juice) with colchicine. West-Ward's unapproved colchicine product label and product insert also fails to mention that patients with renal or hepatic impairment should not be given colchicine in conjunction with P-gp or strong CYP3A4 inhibitors

because these patients face life-threatening and fatal colchicine toxicity even when taken in therapeutic doses. Upon information and belief, West-Ward also provided false, misleading, or incomplete information regarding the FDA approval status of its unapproved colchicine product to Price Lists, which are integrated in pharmacy computer systems, to Wholesaler Ordering Systems, and to other advertising and distribution channels.

Interrogatory No. 12:

Describe with specificity any differences between your COLCRYSTM tablets and West-Ward's colchicine tablets, including, without limitation, any differences with respect to chemical composition, size, strength, or safety.

Response to Interrogatory No. 12:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs object to this Interrogatory on the ground that it is premature because the discovery process is ongoing and this Interrogatory seeks information which will be the subject of expert witness analysis and testimony. Plaintiffs further object on the ground that the term "size" is vague and ambiguous in the context of this Interrogatory, and on the ground that it seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Plaintiffs also object to this Interrogatory on the ground that it calls for the disclosure of confidential and proprietary information.

Subject to and without waiving the foregoing objections, Plaintiffs will respond to this Interrogatory upon entry of a suitable protective order.

Interrogatory No. 13:

Please identify each fact witness whom you believe has knowledge of facts that support, refute, or relate to allegations set forth in your Complaint, and state all such facts you believe to be known to each. Your response should include, but should not be limited to, information responsive to Federal Rule of Civil Procedure 26(a)(1)(A)(i).

Response to Interrogatory No. 13:

Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs object to this Interrogatory on the ground that it is premature because the discovery process is

ongoing. Plaintiffs further object to this Interrogatory to the extent that it calls for information protected by the attorney-client privilege and work-product doctrine. Plaintiffs also object on the ground that this Interrogatory is overly broad and unduly burdensome to the extent it seeks identification of individuals who are not employed by or otherwise managed or controlled by Plaintiffs.

Subject to and without waiving the foregoing objections, Plaintiffs identify the following individuals who have knowledge of facts that support or relate to allegations set forth in Plaintiffs' complaint:

Matthew Davis, M.D., R. Ph.
Vice President of Branded Products/Medical Affairs
Mutual Pharmaceutical Company, Inc.
1100 Orthodox St.
Philadelphia, PA 19124-3131
Tel: 215-288-6500

Subjects of Knowledge: Efforts to obtain FDA approval for Plaintiffs' colchicine product ("COLCRYS")

Gregory Hayer
Senior Vice President of Business Development & Market Access
Mutual Pharmaceutical Company, Inc.
1100 Orthodox St.
Philadelphia, PA 19124-3131
Tel: 215-288-6500

Subjects of Knowledge: Marketing and sales of COLCRYS; use of price lists to market, sell and distribute colchicine products; physician, pharmacist and consumer surveys relating to confusion in the marketplace

Robert Dettery
Vice President of Regulatory Affairs
Mutual Pharmaceutical Company, Inc.
1100 Orthodox St.
Philadelphia, PA 19124-3131
Tel: 215-288-6500

Subjects of Knowledge: Efforts to obtain FDA approval for COLCRYS; FDA regulatory actions regarding unapproved colchicine products; development of COLCRYS product insert, labels, and instructions for use; efforts to register copyrights in COLCRYS product insert

Dwight Hanshew
Senior Vice President of Operations
Mutual Pharmaceutical Company, Inc.
1100 Orthodox St.
Philadelphia, PA 19124-3131
Tel: 215-288-6500

Subjects of Knowledge: Manufacture of COLCRYS and costs relating to same; Acquisition of Colchicine API

Kurt Nielsen, Ph.D.
Executive Vice President of Pharmaceuticals
Mutual Pharmaceutical Company, Inc.
1100 Orthodox St.
Philadelphia, PA 19124-3131
Tel: 215-288-6500

Subjects of Knowledge: Manufacture of COLCRYS and costs relating to same; Acquisition of Colchicine API

Whitney K. Stearns, Jr.
Executive Vice President of Finance & CFO
Mutual Pharmaceutical Company, Inc.
1100 Orthodox St.
Philadelphia, PA 19124-3131
Tel: 215-288-6500

Subjects of Knowledge: Revenues, costs, and profits associated with COLCRYS

Karin A. Kook, Ph.D.
Managing Director & Senior Regulatory Consultant
Salamandra, LLC
One Bethesda Center
4800 Hampden Lane, Suite 900
Bethesda, Maryland 20814-2998
Tel: (301) 652-6110

Subjects of Knowledge: Efforts to obtain FDA approval for COLCRYS

Katherine Bennett, Pharm.D.
Senior Consultant: Clinical
Salamandra, LLC
One Bethesda Center
4800 Hampden Lane, Suite 900
Bethesda, Maryland 20814-2998
Tel: (301) 652-6110

Subjects of Knowledge: Development of COLCRYS product insert, labels, and instructions for use

Brendan Magrab
Executive Vice President of Commercial Operations and General Counsel
Mutual Pharmaceutical Company, Inc.
1100 Orthodox St.
Philadelphia, PA 19124-3131
Tel: 215-288-6500
Subjects of Knowledge: Marketing and sales of COLCRYS

Interrogatory No. 14:

Please identify any witness you may use at trial to present evidence under Federal Rule of Evidence 702, 703, or 705, and for each, provide (i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the data or other information considered by the witness in forming them; (iii) any exhibits that will be used to summarize or support them; (iv) the witness's qualifications, including a list of all publications authored in the previous 10 years; (v) a list of all other cases in which, during the previous 4 years, the witness testified as an expert at trial or by deposition; and (vi) a statement of the compensation to be paid for the study and testimony in the case.

Response to Interrogatory No. 14:

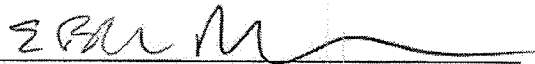
Plaintiffs incorporate the above-stated general responses and objections herein. Plaintiffs object to this Interrogatory on the ground that it is premature because the discovery process is ongoing and the Court has not issued a scheduling order in this Action yet. Plaintiffs further object on the ground that this Interrogatory is compound and attempts to include several separate interrogatories or discreet sub-parts within one purported Interrogatory.

Subject to and without waiving the foregoing objections, Plaintiffs will identify any expert witnesses they intend to call at trial at the appropriate time as required by the Federal Rules of Civil Procedure or by Court order.

Respectfully Submitted,

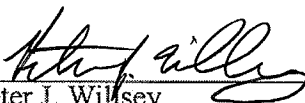
AS TO RESPONSES:

Dated: December 21, 2009


Brendan Magrab
Executive Vice President of Commercial Operations
and General Counsel
Mutual Pharmaceutical Company, Inc.

AS TO OBJECTIONS:

Dated: December 21, 2009


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MUTUAL PHARMACEUTICAL COMPANY, INC., AR
SCIENTIFIC, INC., and AR HOLDING COMPANY, INC.

103504 v3/DC

CERTIFICATE OF SERVICE

I hereby certify that on December 21, 2009, a true and correct copy of the foregoing **PLAINTIFF MUTUAL PHARMACEUTICAL COMPANY, INC.'S OBJECTIONS AND RESPONSES TO DEFENDANT WEST-WARD PHARMACEUTICAL CORP.'S FIRST SET OF INTERROGATORIES** has been served by email, pursuant to the agreement of the parties, to the following individuals:

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Nishant Kottahachchi

EXHIBIT K

Exhibit Filed Under Seal

EXHIBIT L

Exhibit Filed Under Seal

EXHIBIT M

Exhibit Filed Under Seal

EXHIBIT N

Exhibit Filed Under Seal

EXHIBIT O



[Home](#) > [Drugs](#) > [Resources for You](#) > [Information for Healthcare Professionals \(Drugs\)](#)

Drugs

Single-Ingredient Oral Colchicine Video

Title:

Single-Ingredient Oral Colchicine
(May 14, 2010)

Watch Video:

[Windows Media Player](#)¹ (wmv, 08:20:00)
[QuickTime](#)² (.mov, 008:20:00)

[Transcript](#)³



In 2006, CDER's Office of Compliance launched the FDA Unapproved Drugs Initiative to remove unapproved drugs from the market, including a final guidance entitled "Marketed Unapproved Drugs—Compliance Policy Guide (CPG)," outlining its enforcement policies aimed at efficiently and rationally bringing all such drugs into the approval process. The Agency has serious concerns that drugs marketed illegally without required FDA approval may not meet modern standards for safety, effectiveness, quality, and labeling, thereby posing a significant public health concern. The FDA drug approval process provides a review of product-specific information that is critical to ensuring the safety and efficacy of a finished drug product, and ensuring that health care professionals and patients have the information necessary to understand a drug product's risks and its safe and effective use.

Although unapproved colchicine has been used for many years, FDA approved the first single-ingredient oral colchicine product, Colcrys, in July 2009 for the treatment of familial Mediterranean fever (FMF) and acute gout flares; in October 2009 Colcrys was approved for prophylaxis of gout flares (chronic gout). The approved prescribing information for Colcrys includes a new drug interaction warning, updated dosing recommendations and a medication guide. Pharmacists are reminded to dispense only FDA approved products.

[Return to FDA Drug Info Rounds Page](#)⁴

Links on this page:

1. <http://www.accessdata.fda.gov/Videos/cder/druginforounds/colchicine.wmv>
2. <http://www.accessdata.fda.gov/Videos/cder/druginforounds/colchicine.mov>
3. <http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm212566.htm>
4. <http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm>